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104th Congress, 1st Session – – – – – – – – – – House Report 104–436

THE FDA FOOD ADDITIVE REVIEW PROCESS: BACKLOG AND FAILURE TO OBSERVE STATUTORY DEADLINE

FOURTH REPORT

BY THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

together with

ADDITIONAL VIEWS

DECEMBER 21, 1995.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, December 21, 1995.

Hon. NEWT GINGRICH,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Reform and Oversight, I submit herewith the committee's fourth report to the 104th Congress.

WILLIAM F. CLINGER, Jr.,
Chairman.

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104TH CONGRESS, *1st Session* } HOUSE OF REPRESENTATIVES { REPORT 104–436

THE FDA FOOD ADDITIVE REVIEW PROCESS: BACKLOG AND FAILURE TO OBSERVE STATUTORY DEADLINE

DECEMBER 21, 1995.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CLINGER, from the Committee on Government Reform and Oversight, submitted the following

FOURTH REPORT

On December 14, 1995, the Committee on Government Reform and Oversight approved and adopted a report entitled "The FDA Food Additive Review Process: Backlog and Failure To Observe Statutory Deadline." The chairman was directed to transmit a copy to the Speaker of the House.

I. SUMMARY

Food additive petitions must be reviewed and acted upon by the Food and Drug Administration (FDA) "not more than 180 days after the date of filing of the petition."[1] The statutory deadline is not being met and statutory changes are needed to establish more realistic and binding time frames for petition reviews. The regulatory scheme in the United States for food additive review is dysfunctional, and as a result, the American consumer and patient are deprived of technologies that will increase the variety and nutritional benefits of foods, improve diet and advance public health.

Findings:

1. FDA does not meet the 180 day statutory deadline to review and make a decision on food additive petitions.
2. There were 295 pending food additive petitions (direct, indirect, and generally recognized as safe (GRAS)), some of which were filed in the 1970s, as of June 22, 1995.

[1] 21 U.S.C. 348 (c) (2).

3. The lack of fixed deadlines and the increased scientific ability to detect and measure potential hazards have resulted in a review process that is risk-averse.

4. FDA is reluctant to decline incomplete or inadequate petitions, and consequently, allows incomplete and inadequate petitions to remain under review at FDA for more than 180 days.

5. FDA has committed insufficient resources to its food additive review responsibilities.

6. FDA does not set food additive petition review priorities appropriately.

7. FDA's failure to expeditiously review food additive petitions has stifled innovation and introduction of new ingredients by the food industry.

8. A petition review process with no fixed deadlines can be manipulated for anti-competitive purposes.

9. FDA does not make sufficient use of independent scientific resources for food additive petition review.

Recommendations:

1. Congress should amend the Federal Food, Drug and Cosmetic Act review period for food additive petitions, from 180 to 360 days for the most scientifically complex reviews, and the deadline should be strictly observed by FDA.

2. The FDA should recognize that the approval of useful and safe new products can be as important to the public health as preventing the marketing of harmful or ineffective products.

3. The FDA should eliminate the backlog of pending food additive petitions within one year by reallocating the necessary agency resources.

4. The FDA should utilize outside expertise in its evaluation of food additive petitions but retain authority for petition approval.

5. The relevance of the Delaney clause should be studied in view of modern scientific standards so t hat better distinctions can be made between nominal hazards and actual risks.

6. The FDA should amend the review process to prohibit anonymous submissions of data or comments.

II. BACKGROUND

The Human Resources and Intergovernmental Relations (HRIR) Subcommittee began an oversight investigation into the delays in the Food and Drug Administration's (FDA) review and decision making on food additive petitions in April, 1995. This was the first comprehensive oversight investigation into the FDA's management of the food additives program since the food additive amendments were passed in 1958.

The Subcommittee sent document requests to FDA on April 13, April 17, and June 12, 1995. Oversight briefings with FDA were held May 23, June 5, June 9, June 16, June 19, and June 21, 1995. Academicians, former FDA Center for Food Safety and Applied Nutrition (CFSAN) employees, food manufacturers, trade associations, food scientists, and consumer groups were interviewed by the subcommittee staff. HRIR subcommittee hearings were held on June 22 and June 29, 1995.

After the June 22 hearing, a letter from Chairman Christopher Shays and Ranking Member Edolphus Towns was sent to Health and Human Services (HHS) Secretary Donna E. Shalala on June 26, 1995, requesting a legislative proposal that would establish a statutory standard which the FDA could meet in its review of food additive petitions. A follow up letter was sent on August 29, 1995, after no response was received from HHS. A response was received on September 13, 1995. FDA briefed Subcommittee staff on October 2, 1995, on the agency's legislative proposal to rectify the food additive review delays.

The FDA proposes a statutory change which would extend the review period from the current 180 days to 360 days. The agency is committed to reviewing 90% of the petitions within 180 days and proposes administrative performance goals to keep no more than 10% of petitions under review for up to 360 days.

The agency also supports statutory changes which would effect streamlining of the rulemaking process for both food and color additives, increased use of outside experts for review of food and color additive petitions (through amendment of the Federal Advisory Committee Act [2] (FACA)) and conforming amendments for color additives to harmonize deadlines of both food and color additive petitions.

The agency will put more resources and Full Time Equivalent (FTE) positions into the petition review process. The agency may propose user fees to fund pre-filing consultation activities with sponsors.[3]

The Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938 gave the Food and Drug Administration (FDA) authority over food and food ingredients. The Food Additive Amendments to the FFDCA were passed by Congress in 1958 to require FDA's pre-market approval for the use of an additive prior to its inclusion in food. This authority is now found in section 409 of the FFDCA.[4]

An additive is defined as ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.'' This definition covers any substance used in the production, processing, treatment, packaging, transportation or storage of food such as colors, packaging materials, artificial sweeteners and fat substitutes.

Food additives are commonly used to: impart or maintain desired consistency, improve or maintain nutritive value, maintain palatability and wholesomeness, produce texture, control acidity/alkalinity and enhance flavor or impart color. *Direct additives* are added to food for a specific purpose, such as a fat replacer or artificial sweetener. High profile direct additive petitions under review at FDA include: Johnson and Johnson's (McNeil division) SUCRALOSE artificial sweetener and Proctor and Gamble's OLESTRA fat replacer.

Indirect additives may become part of the food in trace amounts due to packaging, storing or other handling. The law also requires the manufacturer to prove an additive's safety for the ways it will

[2] (5 U.S.C. App.) P.L. 92–463, 86 Stat. 770, Oct. 6, 1972.
[3] HRIR interview with FDA Deputy Commissioner William Schultz, October 2, 1995.
[4] 21 U.S.C. 348.

be used in foods, such as for fat replacement, fiber addition, or as a sweetener.

The statutory standard is rigorous but not absolute. An additive is deemed safe if the sponsor proves to a "reasonable certainty that no harm would result from the substance under its intended conditions of use." The amendments also included the Delaney clause which stipulates that "no food additive can be deemed safe if it has been found to induce cancer when ingested by man or animals."[5]

Two groups of substances were exempt from the Food Additives Amendments. They included substances sanctioned by FDA or USDA prior to 1958, such as calcium propionate,[6] and substances considered generally recognized as safe (GRAS), such as salt, sugar, spices, vitamins, etc.[7]

Food additive petitions must be reviewed and acted upon "not more than 180 days after the date of filing of the petition."[8] Upon approval of a food additive petition, FDA issues regulations including the types of foods in which an additive can be used, the maximum amounts to be used, and how additives must be listed on food labels. Meat and poultry additives are reviewed by USDA and FDA.

A. THE REVIEW PROCESS

A sponsor who seeks to market a food additive must submit a petition to FDA establishing that the substance is safe for its intended use and that it performs its intended function. FDA evaluates the adequacy of the petition for evaluation and the need for scientific evaluation outside FDA's Center for Food Safety and Applied Nutrition (CFSAN). The petition is simultaneously reviewed by the Division of Product Manufacturing, the Division of Health Effects Evaluation, the Division of Molecular Biology and other CFSAN offices as determined by CFSAN's Office of Premarket Approval at the time of submission.

Under the National Environmental Policy Act (NEPA), FDA must evaluate the potential environmental effects of the substance and include this evaluation in its decision-making. A safety determination is made, an administrative record is compiled and a rule is drafted. The petition receives a legal review by FDA General Counsel and a policy review by the Office of the Commissioner before publication in the Federal Register and then in the Code of Federal Regulations. A food additive regulation is not a product license limited to a single sponsor or manufacturer. Any manufacturer may market an approved food additive under approved conditions of use.[9]

Few, if any, food additive petitions are acted upon in the statutorily-prescribed time period. Frequently, food additive petitions remain in pending status, while the agency asks for more data. At a meeting on June 16, 1995 with Subcommittee staff, FDA Deputy Commissioner for Policy William Schultz stated that the 180 day review period was unrealistic and that he felt no one in industry

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[5] Pub. L. No. 85–929, 4, 72 Stat. 1785 (1958), as amended, 21 U.S.C. 348(c) (3) (A) (1982).
[6] Section 201 (s) (4) of the FFDCA, 21 U.S.C. 321 (s) (4).
[7] 21 CFR 182.1 (a).
[8] 21 U.S.C. 348 (c) (2).
[9] HRIR Hearings, p. 5 (testimony of Linda Suydam).

or at the FDA thought it realistic to expect reviews to be completed in 180 days.

B. FOOD ADDITIVE DELAYS

FDA has a backlog of 295 food additive petitions under review, some of which have been pending since the 1970s. Approximately 100 new food and color additive petitions are submitted to the FDA each year.

Indirect additives comprise approximately half of all pending petitions, and are believed by many industry sources to be languishing due to low priority within the Center.[10] Direct additives comprise approximately 17% of pending petitions and may be under review for up to 10 years while agency reviewers ascertain their safety, often with repeated requests for additional animal studies and safety data.

For example, McNeil's SUCRALOSE petition was filed with FDA in February, 1987, but has not yet been approved. It was filed in Canada and Australia in April and June, 1987, and approved in Canada in September, 1991. Australia's National Food Authority announced its intention to approve SUCRALOSE subject to a public comment period and consideration by the National Food Standards Council (which is comprised of public health ministers at State, Territory, and Federal levels) in December 1991. Final Australian approval was received in October, 1993.[11]

C. GRAS DELAYS

In March 1972, the FDA contracted with the Federation of American Societies of Experimental Biology (FASEB) to evaluate the safety and health effects of over 468 food additives considered generally recognized as safe or "GRAS" at the time of the 1958 amendments. In March 1982, FASEB completed its evaluation of 422 direct additives and 46 indirect additives. It determined that 339 or 72% were considered GRAS with no evidence of adverse health effects. Sixty-nine or 15% were GRAS with additional data required if increased or new uses are contemplated.

Twenty-one or 5% were permitted to receive an interim food additive regulation requiring that testing be undertaken but given GRAS status until such tests are completed and evaluated. Five or 1% had insufficient evidence to determine if reported adverse health effects were not deleterious. It was recommended that safe conditions of use be established for these five additives.

Thirty-four or 7% had inadequate data on biological studies which precluded evaluation. An invitation to submit data was recommended, and if none was received, there was a recommended recision of GRAS status. A number of GRAS substances reviewed by FASEB have yet to be acted upon by FDA.

GRAS petitions are not required by law but are voluntarily submitted to obtain FDA concurrence that premarket approval is not required. However, due to liability concerns, processed foods manu-

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[10] *Delays in the FDA's Food Additive Petition Process and GRAS Affirmation Process: Hearings Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight*, 104th Cong., 1st Sess. 131–132 (1995) ("HRIR Hearings") (statement of Jerome Heckman).

[11] McNeil chronology document in Subcommittee files.

facturers are increasingly unwilling to purchase GRAS substances without an affirmation letter from FDA. Seventy-five GRAS affirmation petitions are currently pending at FDA, the oldest of which was filed on August 31, 1972.

On June 22, 1995, the FDA presented at the Subcommittee hearing an administrative plan to rectify the backlog and address delays in the food additives program. The plan included:

- reorganization of FDA's Center for Food Safety and Applied Nutrition (CFSAN) to place petition review resources under one central manager;
- development and issuance of a "threshold of regulation" approach for indirect additives that meet specific criteria;
- performance goals to review petitions within defined time periods;
- reform of the GRAS regulatory process;
- additional agency resources to reduce the inventory of pending petitions;
- use of external scientific expertise to expedite the review of pending petitions;
- elimination or reduction of requirements for environmental assessments for many petitions;
- expanded programs to help petitioners submit complete, sufficient submissions.[12]

III. FINDINGS

1. FDA does not meet the 180 day statutory deadline to review and make a decision on food additive petitions.

The agency views the 180 day statutory time frame as a goal, not a binding requirement. FDA Interim Deputy Commissioner for Operations Linda Suydam testified that the agency views the 180 day time frame as "a target, and we try to meet that target."[13]

The FDA does not meet the 180 day target. Data supplied by FDA at the June 22, 1995 hearing indicate that since 1970, the average time to approval of a direct food additive has been at least 20 months.[14] FDA General Counsel Margaret Jane Porter stated that, in her view, the 180 day statutory limit was "ridiculous."[15] Chairman Shays stated at the June 22 hearing that "the statutory deadline has been interpreted out of existence by the FDA, and I am eager to learn how the agency plans to restore accountability to the process for determining the safety of food additives."[16]

FDA testified that the establishment of performance goals for the food additive petition review process will provide a mechanism to fulfill the Agency's commitment to timely and predictable decision making.[17] However, the plan submitted by the agency to relieve the backlog of pending petitions[18] was not in compliance with the statute.[19]

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[12] HRIR Hearings, p. 10–11 (statement of Linda Suydam).
[13] HRIR Hearings, p. 26.
[14] HRIR Hearings, p. 16, FDA supplied chart.
[15] HRIR Hearings, p. 25.
[16] HRIR Hearings, p. 2 (statement of Chairman Christopher Shays).
[17] HRIR Hearings, p. 13 (statement of Linda Suydam).
[18] Ibid.
[19] HRIR Hearings, p. 25–27.

2. As of June 22, 1995, there were 295 pending food additive petitions (direct, indirect, and GRAS), some of which were filed in the 1970s.

The FDA provided the Subcommittee with a list of 295 pending food petitions.[20] Sixty-six percent of pending petitions were filed between 1990–1994, 27% between 1980–1989, and 7% between 1971–1979.[21]

3. The lack of fixed deadlines and the increased scientific ability to detect and measure potential hazards have resulted in a review process that is risk-averse.

Under-funding and under-staffing of the CFSAN were cited by FDA and academic witnesses[22] as impediments to timely scientific review, sound scientific judgement, and support for new food technologies. However, the inability of CFSAN reviewers to recognize the degree of actual risk, [23] or no risk, posed by low levels of materials as used in practice, as opposed to materials which present a minimal or theoretical hazard at much higher levels, was also identified as an impediment to timely review of food petitions.[24]

The statutory charge is to determine the safety of food additives, applying the best science available, not an absolute standard of zero risk. FDA regulations define safety as "the reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance."[25]

4. The FDA is reluctant to decline incomplete or inadequate petitions, and consequently, allows incomplete and inadequate petitions to remain under review at FDA for more than 180 days.

FDA stated that industry prefers a longer review time to a refusal to file or rejection of a petition.[26] Industry is unwilling to push FDA for a decision on a food additive because companies fear rejection of the petition.[27]

The quality of submitted petitions is often inadequate. FDA expressed support for an industry proposal that would assist petitioners in developing their food additive petitions prior to submission to the FDA.[28] Pfizer and other food companies have developed a proposal to use expert scientists to review the scientific data of food additive petitions that are submitted to FDA.

Under the proposal, as the petitions are submitted the relevant safety sections would also be submitted to expert panels, which would be selected and administered by an independent, third party institution. This plan would be funded by annual grants from ingredient suppliers and food companies and the expert panels would

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[20] HRIR Hearings, p. 24, FDA supplied chart.
[21] Letter of May 2, 1995 FDA response to Chairman Shays inquiry (in subcommittee files).
[22] HRIR Hearings, p. 35–37 (statement of Dr. Sanford Miller).
[23] Ibid.
[24] HRIR Hearings, p. 49.
[25] 21 CFR. 170. 3(i); HRIR Hearings, p. 41 (statement of Dr. Richard Hall).
[26] HRIR Hearings, p. 10 (statement of Linda Suydam); p. 23.
[27] HRIR Hearings, p. 10 (statement of Linda Suydam); p. 105–106.
[28] HRIR Hearings, p. 19.

be funded by an assessment fee for each petition. Panel reports and recommendations would be submitted by the petitioner to the FDA but FDA would retain approval authority.[29]

5. FDA has committed insufficient resources to its food additive review responsibilities.

FDA has taken resources from the food programs, which comprise more than 50% of the agency's responsibilities,[30] and devoted them to drug and biologic reviews.[31]

Allocation of internal resources by FDA management jeopardizes the food programs. In FY 1994 the total FDA budget was $873,048,000 of which $221,648,000, or 25%, were devoted to food regulation.[32] However, foods represent more than 50% of FDA's workload.

The CFSAN staffing levels are about the same as 10 years ago after dropping to their lowest levels in FY1989. Comparison with budget changes for the Centers for Drugs and Biologics shows a 60% increase for the drug and biologics programs while CFSAN staffing remains at the same level.[33]

The leveling of FDA resources for foods in recent years is in sharp contrast with the increased responsibilities CFSAN has assumed due to new legislation in the areas of nutrition labeling,[34] nutrition monitoring, pesticide monitoring, and safe transport of food. The food supply for which FDA is responsible has grown enormously in the number of food products and in diversity of source and processing since the FFDCA was enacted in 1906 and the food additive amendments were enacted in 1958.

The Prescription Drug User Fee Act (PDUFA)[35] allows user fees to be used as a supplement to the FDA's appropriated budget only if FDA allocates funding for drug and biologics programs at 1992 inflation adjusted levels. FDA Interim Deputy Commissioner for Operations Linda Suydam testified that "as a result (of PDUFA), the other parts of the agency's programs have to take cuts to make up for that large program being protected."[36]

6. FDA does not set food additive petition review priorities appropriately.

Seventy-five percent of food additive petitions are for indirect additives and 25% are for direct additives.[37] Indirect additives generally require fewer resources and less review than direct additives.[38] However, the FDA does not assign greater resources to direct petitions as opposed to indirect petitions, instead utilizing a "first in, first out" review system which does not devote the greatest resources to the applications with the greatest resource requirements.

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[29] HRIR Hearings, p. 163 (statement of Donald Farley).
[30] FDA Almanac FY1994, p. 68.
[31] HRIR Hearing, FDA Centers Personnel Chart, p. 60.
[32] FDA Almanac FY1994, FDA's Budget Chart, p. 11.
[33] HRIR Hearings, FDA Center Personnel Chart, p. 61.
[34] HRIR Hearings, p. 41 (statement of Dr. Richard Hall).
[35] 21 U.S.C. 379(h).
[36] HRIR Hearings, p. 28.
[37] HRIR Hearings, p. 31.
[38] HRIR Hearings, p. 139–141 (statement of Jerome Heckman).

7. FDA's failure to expeditiously review food additive petitions has stifled innovation and introduction of new ingredients by the food industry.

The food industry, which is now international in nature, is extremely adverse to taking risks in the introduction of new products. If new technologies have to undergo long periods of review without decision by the agency, the result is an industry which tends to repeat past technologies rather than developing new ones.[39] Several companies told the Subcommittee staff in interviews that they had abandoned research into promising food additives because of the delays in the petition review process. One company testified that consideration had been given to "abandoning our U.S. based research."[40]

8. A petition review process with no fixed deadlines can be manipulated for anti-competitive purposes.

The FDA received safety objections regarding petitions under review from anonymous sources which may have been motivated by economic, social, or political forces.[41] Industry representatives believe that the review process has been manipulated to cause delays.[42] FDA admitted that this is a problem with the current system.[43]

9. FDA does not make sufficient use of independent scientific resources for food additive petition review.

FDA cannot maintain sufficient scientific expertise in all areas necessary for review of more complicated and scientifically advanced petitions. Industry sources report that FDA review of macroingredient[44] petitions in particular now requires an increasing reliance on nutritional and clinical studies as opposed to traditional toxicological studies in test animals. Therefore, FDA requires access to more human and veterinary medical reviewers and nutritionists as opposed to toxicologists.

Toxicology reviews of food additive petitions were listed as a significant source of delay at FDA. Former FDA toxicologists and industry regulatory affairs professionals cited a lack of scientific resources and confidence in toxicology personnel.[45] FDA has inadequate access to top-level expertise in toxicology, especially experienced risk assessment personnel.[46]

The FDA presented a plan to utilize existing contracts with independent, third-party scientific organizations to aid the agency's review of food additive petitions.[47] In order to keep up with increasing industry requirements for food additive reviews, FDA must look

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[39] HRIR Hearings, p. 35–36 (statement of Dr. Sanford Miller).
[40] HRIR Hearings, p. 162–163 (testimony of Mr. Donald Farley).
[41] HRIR Hearings, p. 40 (testimony of Dr. Richard Hall);p. 90–91; p. 101 (statement of Dr. Wayne Callaway); see also p. 181 (statement of Dr. Michael Jacobson)
[42] HRIR Hearings, p. 40 (testimony of Dr. Richard Hall), p. 43 (statement of Dr. Richard Hall).
[43] HRIR interview with Deputy Commissioner William Schultz, October 2, 1995.
[44] "An element of carbon, hydrogen, oxygen, or nitrogen, needed in large amounts for plant growth and development." *Webster's II New Riverside University Dictionary (1988).*
[45] HRIR Hearings, p. 41 (statement of Dr. Richard Hall).
[46] HRIR Hearings, p. 163 (statement of Mr. Donald Farley).
[47] HRIR Hearings, p. 12 (testimony of Linda Suydam).

outside the agency for additional scientific review resources to supplement agency resources.[48]

IV. RECOMMENDATIONS

1. Congress should amend the Federal Food, Drug and Cosmetic Act review period for food additive petitions, from 180 to 360 days for the most scientifically complex reviews, and the deadline should be strictly observed by FDA.

The 180 day time frame has been meaningless for many years as evidenced by the list of 295 pending petitions submitted by FDA to the Subcommittee. Food manufacturers need "some finality to the process of additive review . . . deadlines for (agency) actions that are appropriate and real, and not merely advisory."[49]

Also, the 180 day statutory deadline for FDA approval/disapproval decisions on food additive applications is no longer sufficient for technologically advanced applications such as food products derived through biotechnology, macroingredients and functional foods, which are defined "as any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains"[50] that provide specific health benefits.

The food industry would support a meaningful review deadline. Industry representatives presented a proposal for a new food additive review system with review time frames of at least 360 days.[51] This proposal would, for the first time, permit an FDA selected independent scientific review panel to assess the safety of a food additive and make a recommendation to FDA regarding approval or disapproval.

Under such a review process, the agency must either accept the recommendation and issue a regulation allowing use of the food additive or reject the recommendation and cite the reasons for so doing. For the first time, the review process would have a fixed deadline, after which a presumption of approval would apply. To overcome the presumption of approval, FDA would bear the burden of proof to rebut the third party recommendation.

If the agency did not review and make a decision on the review panel's recommendation within statutorily prescribed time frames, the recommendation of the scientific review panel would become effective. The presumption of approval arising from a favorable recommendation from the scientific review organization will ensure that FDA meets the statutory deadline or takes final (appealable) administrative action to extend it.

The FDA presented performance goals in testimony that indicate that most petitions could be reviewed by the agency within 360 days.[52]

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[48] HRIR Hearings, p. 49.
[49] HRIR Hearings, p. 119 (testimony of Stuart Pape).
[50] *Journal of the American Dietetic Association*, "Position of the American Dietetic Association: Phytochemicals and functional foods," p. 493, April 1995 Volume 95 Number 4.
[51] HRIR Hearings, p. 120 (statement of Stuart Pape).
[52] HRIR Hearings, p. 13 (statement of Linda Suydam).

2. The FDA should recognize that the approval of useful and safe new products can be as important to the public health as preventing the marketing of harmful or ineffective products. FDA's prompt approval of new food petitions can also benefit the environment.

The 1988 Surgeon General's Report on Nutrition and Health stated that "The public would benefit from increased availability of foods and food products low in calories, total fat, saturated fat, cholesterol, sodium and sugars."[53] Physicians testified that many patients with chronic conditions would more successfully implement long-term dietary modifications if they had a greater variety of new foods with lower fat, calories, sugars, and sodium.[54] A consumer group witness testified that reducing saturated fat intake by eight grams a day would save as much as $24 billion a year.[55]

The FDA should implement Recommendation 1.4 of the Advisory Committee on the Food and Drug Administration, which states "FDA must recognize the approval of useful and safe new products can be as important to the public health as preventing the marketing of harmful or ineffective products. Specifically, the FDA should develop a flexible range of regulatory pathways, all of which uphold current standards of safety and efficacy, but which reflect the fact that not all drugs, devices and foods are alike."[56]

FDA's prompt approval of indirect food additives for use in new and improved food packaging can also have significant environmental benefits. The food industry is a primary consumer of packaging materials. Improvements in source reduction and recycling of materials can result in immediate environmental benefits.[57]

3. The FDA should eliminate the backlog of food petitions within one year by reallocating the necessary resources to the food petition review program.

After the HRIR investigation into the backlog of food additive petitions began, FDA informed the Subcommittee staff that twenty-five individuals have been reassigned within CFSAN to work on food petitions and two toxicologists from the National Center for Toxicological Research (NCTR) have been devoted to CFSAN food petition toxicology reviews. FDA will hire immediate contract help to focus on chemical, toxicological and environmental reviews of low priority petitions.[58] Furthermore, FDA testified that $7 million was added to the indirect additive review program to eliminate the backlog.[59]

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[53] The Surgeon General's Report on Nutrition and Health, 1988, U.S. Department of Health and Human Services, p. 19.

[54] HRIR Hearings, p. 99–100 (statement of Dr. C. Wayne Callaway); p. 102 (testimony of Dr. Michael Davidson).

[55] HRIR Hearings, p. 182 (statement of Dr. Michael Jacobson).

[56] Final Report of the Advisory Committee on the Food and Drug Administration, U.S. Department of Health and Human Services, May 1991, p. 14.; HRIR Hearings, p. 53 (testimony of Dr. Stephen Ziller).

[57] HRIR Hearings, p. 92–93 (testimony of Dr. D. Stephen Saunders).

[58] HRIR Interview with FDA Deputy Commissioner for Policy William Schultz; October 2, 1995.

[59] HRIR Hearings, p. 22 (testimony of Linda Suydam).

4. The FDA should utilize outside expertise in its evaluation of food additive petitions in order to reach prompt and responsible decisions on the safety of these products. The FDA should retain responsibility for petition approvals.

Utilization of outside scientific expertise will provide FDA with access to a wider range of expertise and extend the agency's scientific resources. FDA proposed to award a contract for independent third-party scientific review of some indirect additive petitions as part of its administrative reform proposal.[60]

Food scientists and industry witnesses proposed a system whereby an independent third party scientific review organization may review a petition and find an additive safe for its intended use. FDA must concur with the scientific review or the agency may refuse to do so only on the basis of explicitly stated, substantially supported countervailing considerations. If FDA does not issue a regulation or report defending an opposing view within a prescribed time, then presumptive approval would become final.[61] The FDA must select the appropriate extramural review group and it must set the criteria for selection of members of the review panels of these groups to avoid the appearance of a conflict of interest and lack of public confidence in the process.[62]

The agency should be encouraged to sort out those issues which the agency itself must resolve as opposed to those which may pose lesser risk and which may be scientifically reviewed by external groups under the agency's authority. Industry witnesses support retention of final decision making by the FDA.[63] Consumer groups expressed support for utilization of third-party toxicology reviews with retention of final approval authority by FDA.[64]

5. The relevance of the Delaney clause should be studied in view of modern scientific standards so that better distinctions can be made between nominal hazards and actual risks.

The Delaney clause stipulates that no food additive can be deemed safe if it has been found to induce cancer when ingested by man or animals. The Delaney clause was enacted at a time when it was not possible to detect the presence of chemicals at ratios of as little as .02 parts per trillion. This scientific advancement may require implementation of more subtle risk based approaches. In addition, some substances at minimal levels present no risk to humans through consumption. The agency should establish a level of acceptable risk for food additives, below which there is no hazard to humans through consumption under normal or intended use.[65]

6. The FDA should amend the review process to prohibit anonymous submissions of data or comments.

Companies have utilized anonymous submissions of data to delay review of competitors' products.[66] Manipulation of the food additive

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[60] HRIR Hearings, p. 12 (statement of Linda Suydam).
[61] HRIR Hearings, p. 36 (statement of Dr. Sanford Miller)
[62] Ibid.
[63] HRIR Hearings, p. 40, 44 (statement of Dr. Richard Hall); p. 119 (testimony of Stuart Pape).
[64] HRIR Hearings, p. 175 (testimony of Dr. Michael Jacobson).
[65] HRIR Hearings, p. 50.
[66] HRIR Hearings, p. 40 (testimony of Dr. Richard Hall);p. 90–91; p. 101 (statement of Dr. Wayne Callaway); see also p. 181 (statement of Dr. Michael Jacobson).

review process for anti-competitive purposes is inconsistent with the purposes of pre-market review. FDA should prohibit the consideration of information from anonymous sources.

ADDITIONAL VIEWS OF HON. DAVID M. MCINTOSH AND HON. MARK E. SOUDER

The Committee's report offers a candid assessment of the problems that plague the FDA's food approval process. With nearly 300 food additive petitions pending with the FDA (some that were filed in the 1970's), it is obvious that the system in place at the FDA today is not capable of meeting the current statutory mandate that all food additive applications be approved or declined within 180 days of submission. The Committee's recommendations are sound ones that should be well accepted by the food industry, consumer groups, and the FDA. Unfortunately, I am concerned that the enforcement mechanisms for the Committee's recommendations are inadequate.

Currently, the FDA's delay in approving food additives is caused by inertia within the agency. While that inertia can be somewhat alleviated through instructions to do better, I am convinced that it cannot be eliminated without a significant enforcement hammer. I am particularly concerned that the recommendations include a relaxation of the statutory deadline for a decision on a food additive from 180 to 360 days.

While relaxing the statutory deadline makes some sense, it also makes sense to transform it into a meaningful one. If the time frames in the Government Reform and Oversight Report were expected to be 360 days, then after a brief period—90 days perhaps—the statute should provide FDA with three options: (1) issue a regulation approving the use of the additive, (2) disapprove the use of the additive, but only if FDA can demonstrate that an additive has not been found to be safe, or (3) if FDA fails to do either, the additive is deemed to be approved. In this way, FDA is provided an incentive to engage in a real cost/benefit analysis in the allocation of its resources. I am convinced that unless hammers such as this one are incorporated into the regulatory schemes we have developed, we are destined to see agencies fail to meet statutory deadlines and justify their failures with claims of too much work and too few resources.

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